DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Objective Work Plan (OWP), Objective Progress Report (OPR) and Project Abstract.

OMB No.: 0980–0204.

Description: Content changes are being made to the OPR only. The information in the OPR is being collected on a quarterly basis to monitor the performance of grantees and better gauge grantee progress. The standardized format will allow ANA to report results across all its program areas and flag grantees that may need additional training and/or technical assistance to successfully implement their projects.

Following are content changes being made within specific sections of the OPR form:

Objective Work Plan Udate Section: Adding 1st through 4th Quarter (Q1,Q2,Q3,Q4) results for Activities within each Objective. The grantee can continue to add to this form each quarter (rather than on to a new form), reflecting cumulative results throughout the project period rather than just the quarter.

Financial Section: Add 2 Questions: (1) Provide details on any income generated as a result of ANA project activities; (2) Provide details on any changes made to the budget during the reporting period.

Native American Youth and Elder Opportunities Section: Add Question: (1) Request details on any intergenerational activities between grandparents and their grandchildren.

Finally, add a new section (last section) to the form:

Project Sustainability: (1) Request details on the grantee's intention to continue the project benefits and/or services after the project period has ended.

End of Content Changes to the OPR.

No changes are being made to the OWP or to the Project Abstract (below).

The information collected by the OWP is needed to properly administer and monitor the Administration for Native Americans (ANA) programs within the Administration for Children and Families (ACF). The OWP assists applicants in describing their projects' objectives and activities, and also assists independent panel reviewers, ANA staff and the ANA Commissioner during the review and funding decision process.

The Project Abstract provides crucial information in a concise format that is utilized by applicants, independent reviewers, ANA staff and the ANA Commissioner.

Respondents: Tribal Government, Native non-profit organizations, Tribal Colleges & Universities

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OWP	500	1	3	1,500
OPR	275	4	1	1,100
Project Abstract	500	1	0.50	250

Estimated Total Annual Burden Hours: 2,850.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: March 6, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–5283 Filed 3–11–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0228]

Determination of Regulatory Review Period for Purposes of Patent Extension; PROFENDER

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PROFENDER and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a

product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product PROFENDER (emodepside, praziquantel). PROFENDER is indicated for the treatment and control of hookworm infections caused by *Ancylostoma tubaeforme* (adults, immature adults, and fourth stage larvae), roundworm infections caused by *Toxocara cati* (adults and fourth stage larvae), and tapeworm infections caused by *Dipylidium caninum* (adults) and *Taenia taeniaeformis* (adults) in cats. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PROFENDER (U.S. Patent No. 5,514,773) from Astellas Pharma Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 10, 2008, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of PROFENDER represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for PROFENDER is 1,585 days. Of this time, 1,542 days occurred during the testing phase of the regulatory review period, while 43 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the act (21 U.S.C. 360b(j)) became effective*: February 27, 2003. The applicant claims June 2, 2000, as the date the investigational new animal drug application (INAD) became effective. However, the date that a major health or environmental effects test is begun or the date on which the agency acknowledges the filing of a notice of claimed investigational exemption for a new animal drug, whichever is earlier, is the effective date for the INAD. According to FDA records, February 27, 2003, is the effective date for the INAD.

2. *The date the application was initially submitted with respect to the animal drug product under section 512 of the act*: May 18, 2007. The applicant claims May 15, 2007, as the date the new animal drug application (NADA) for PROFENDER (NADA 141–275) was initially submitted. However, a review of FDA records reveals that NADA 141–275 was initially submitted on May 18, 2007.

3. *The date the application was approved*: June 29, 2007. FDA has verified the applicant's claim that NADA 141–275 was approved on June 29, 2007.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,314 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by May 11, 2009. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 8, 2009. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 24, 2009.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E9–5374 Filed 3–11–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 3, 2009, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd, Silver Spring, MD. The hotel telephone number is 301–589–5200.

Contact Person: Janie Kim, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *janie.kim@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington DC area), code 3014512530. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.